

Pharmaceutical Science, CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

(ii) The Directors and Deputy Directors of the divisions in Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2)(i) For drug products listed in § 314.440(b) and submitted under §§ 314.50, 314.70, and 314.94 of this chapter:

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in §§ 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests are not included in this paragraph.

(1) The Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(3) Associate Director for Chemistry, Office of Pharmaceutical Science, CDER.

(e) The Director, Division of Labeling and Program Support, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, are authorized to perform all the functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in §§ 314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests is not included in this paragraph.

(f) The supervisory and team leader chemists in the Divisions of New Drug Chemistry I, II, and III, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in §§ 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in § 5.10(a) and paragraphs (a) and (b) of this section.

[49 FR 14935, Apr. 16, 1984, as amended at 50 FR 30697, July 29, 1985; 50 FR 47207, Nov. 15, 1985; 52 FR 37764, Oct. 9, 1987; 54 FR 8319, Feb. 28, 1989; 55 FR 6247, Feb. 22, 1990; 55 FR 51688, Dec. 17, 1990; 57 FR 17980, Apr. 28, 1992; 58 FR 17094, Apr. 1, 1993; 59 FR 33431, June 29, 1994; 60 FR 57338, Nov. 15, 1995; 62 FR 2557, Jan. 17, 1997]

§ 5.81 Responses to Drug Enforcement Administration temporary scheduling notices.

The Associate Commissioner for Health Affairs is authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under the Controlled Substances Act, as amended (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 811(h)(4), as amended hereafter). The delegation excludes the authority to submit reports to Congress.

[60 FR 54424, Oct. 24, 1995]

§ 5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, Deputy Center Director for Review Management, and

Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research, for those drugs listed in § 314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

[54 FR 8319, Feb. 28, 1989, as amended at 62 FR 2558, Jan. 17, 1997]

§ 5.83 Approval of new animal drug applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted pursuant to section 512 of the act:

(1) The Director, the Deputy Director for Human Food Safety and Consult-

ative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to new animal drug applications that are described by § 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Chemistry, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of applications for animal feeds containing new animal drugs:

(1) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(2) The Chief, Petition Review and Medicated Feeds Branch, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Medicated Feeds Specialist, Petition Review and Medicated Feeds Branch, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

[49 FR 14937, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 53 FR 2225, Jan. 27, 1988; 53 FR 17186, May 16, 1988; 53 FR 40055, Oct. 13, 1988]

§ 5.84 Issuance of notices, proposals, and orders relating to new animal drugs and feeds bearing or containing new animal drugs.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and feeds bearing or containing new animal drugs, submitted pursuant to section